subpart E of part 807 of this chapter subject to the limitations in § 880.9.

[65 FR 36326, June 8, 2000]

§ 880.6900 Hand-carried stretcher.

(a) *Identification.* A hand-carried stretcher is a device consisting of a lightweight frame, or of two poles with a cloth or metal platform, on which a patient can be carried.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682–69737, Oct. 21, 1980, as amended at 59 FR 63011, Dec. 7, 1994]

§ 880.6910 Wheeled stretcher.

(a) *Identification.* A wheeled stretcher is a device consisting of a platform mounted on a wheeled frame that is designed to transport patients in a horizontal position. The device may have side rails, supports for fluid infusion equipment, and patient securement straps. The frame may be fixed or collapsible for use in an ambulance.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

[45 FR 69682–69737, Oct. 21, 1980, as amended at 63 FR 59229, Nov. 3, 1998]

§ 880.6920 Syringe needle introducer.

(a) *Identification.* A syringe needle introducer is a device that uses a spring-loaded mechanism to drive a hypodermic needle into a patient to a predetermined depth below the skin surface.

(b) *Classification.* Class II (performance standards).

§ 880.6960 Irrigating syringe.

(a) *Identification.* An irrigating syringe is a device intended for medical purposes that consists of a bulb or a piston syringe with an integral or a detachable tube. The device is used to irrigate, withdraw fluid from, or instill fluid into, a body cavity or wound.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807. If the device is not labeled or otherwise represented as sterile, it also is exempt from the good manufacturing practice regulation in part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 880.6970 Liquid crystal vein locator.

(a) *Identification.* A liquid crystal vein locator is a device used to indicate the location of a vein by revealing variations in the surface temperature of the skin by displaying the color changes of heat sensitive liquid crystals (cholesteric esters).

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 69682–69737, Oct. 21, 1980, as amended at 54 FR 25050, June 12, 1989]

§ 880.6980 Vein stabilizer.

(a) *Identification.* A vein stabilizer is a device consisting of a flat piece of plastic with two noninvasive prongs. The device is placed on the skin so that the prongs are on either side of a vein and hold it stable while a hypodermic needle is inserted into the vein.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807. If the device is not labeled or otherwise represented as sterile, it is also exempt from the good manufacturing practice regulation in part 820, with the exception of § 820.180, general requirements concerning records, and § 820.198, with respect to complaint files.

§ 880.6990 Infusion stand.

(a) *Identification.* The infusion stand is a stationary or movable stand intended to hold infusion liquids, infusion accessories, and other medical devices.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in

subpart E of part 807 of this chapter subject to the limitations in §880.9.

[63 FR 59718, Nov. 5, 1998]

PART 882—NEUROLOGICAL DEVICES

Subpart A—General Provisions

Subpart B—Neurological Diagnostic Devices

Subparts C–D [Reserved]

Subpart E—Neurological Surgical Devices

Subpart F—Neurological Therapeutic Devices